REMARKS

With this Amendment, claim 1 has been amended. Claims 1-5, 7-9, 11-13, 37 and 38 are pending in this application. Claims 39-43 are withdrawn from consideration.

Support for amended claim 1 may be found at least at page 15, line 23 to page 16, line 2 of the specification as filed. No new matter has been added by this Amendment.

Applicants respectfully request reconsideration of the claims of this application in view of the following comments.

Compliance of Claims 1-4 With 35 U.S.C. §102

The Office Action rejects claims 1-4 as being anticipated by Trogolo et al. US 6,436,422. Applicants respectfully request reconsideration of this rejection.

As understood by Applicants, Trogolo et al. relates to a hydrophilic polymer coating having antimicrobial properties. The hydrophilic polymer coating may have antibiotic ceramic particles dispersed therein. In this regard, see e.g. the following portions of Trogolo et al.:

- "The coating composition is formed of a hydrophilic polymer having antibiotic ceramic particles, preferably antibiotic zeolite, dispersed therein." (at Abstract).
- "According to the present invention, an antibiotic hydrophilic composition is used to coat a substrate. The composition contains a hydrophilic polymer having antibiotic ceramic particles dispersed therein." (column 3, lines 17-20).
- "The substrate employed in accordance with the invention may be any substrate to which the hydrophilic polymer adheres..." (column 5, lines 41-43).
- "A primer may be applied to the substrate before applying the solution polymer to help bond the hydrophilic polymer to the substrate." (column 6, lines 56-58).

Accordingly, Trogolo et al. do not teach hydroxyapatite coatings on stents as contended in the Office Action, but rather teach a hydrophilic polymer coating that may have antibiotic ceramic

particles dispersed therein. Further, Trogolo et al. do not teach a "flexible calcium phosphate coating" as required by amended claim 1 and dependent claims 2-4. The Examiner is therefore respectfully requested to withdraw this rejection.

Compliance of Claims 1-4, 7, 9, 12 and 13 with 35 U.S.C. §103

The Office Action rejects claims 1-4, 7, 9, 12 and 13 as being unpatentable over Gao et al. US 6,113,993 and Pacetti et al. US 2002/0123801. Applicants respectfully request reconsideration of this rejection.

To Applicants' understanding, Gao et al. do not teach the application of a flexible calcium phosphate coating to a flexible substrate such as a stent. As understood, Gao et al. teach a method of coating a substrate with a calcium phosphate compound, and "the coated substrate is preferably used as an implant, including but not limited to orthopaedic, dental and combinations thereof" (see Gao et al. at Abstract). The field of the invention states that the invention "relates to a method of coating a substrate with a calcium phosphate compound as an implant for bone or tooth or as an optical device" (Gao et al., column 1, lines 12-14). Gao et al. teach that "[t]he substrate is a solid material..." (column 3, line 4). Gao et al. do not teach that the substrate may be a flexible substrate such as a stent.

Pacetti et al., as understood, teach a polymeric coating for implantable devices or endoluminal prostheses, including e.g. stents, wherein the coating contains particles and serves as a barrier layer. In embodiments, a reservoir coating comprising an active ingredient dispersed in a polymer is applied to the stent (see e.g. paras. [0048]-[0049]). In embodiments, a rate-reducing membrane or diffusion barrier layer having a polymeric coating with particles dispersed therein is applied thereto, wherein the particles are of an inorganic or organic type that have barrier-type properties (see e.g. paras. [0065]-[0070]). The particles may include calcium salts such as hydroxyapatite. Again, Applicants emphasize that Pacetti et al. do not teach or suggest the coating of a flexible substrate such as a stent with a calcium phosphate such as hydroxyapatite. Rather, Pacetti et al. teach a polymeric coating for a stent, which may have particles of calcium salts dispersed therein.

One skilled in the art would understand that a polymeric coating is flexible, and would expect that a polymeric coating would be suitable for application to a flexible substrate such as a stent. In contrast, calcium phosphate ceramics are commonly considered to be inflexible and brittle. One skilled in the art would not have considered an inflexible and brittle material as a suitable coating for a stent, which undergoes significant radial deformation when transforming from an initially crimped (contracted) form when packaged and stored, to the final radially expanded state when implanted in an artery.

One skilled in the art would not be motivated to combine the teachings of Gao et al. with Pacetti et al. because a person seeking to coat a flexible substrate, such as a stent, would not look to documents dealing with calcium phosphate coatings, such as Gao et al., since the prevailing wisdom in the art was that calcium phosphate coatings are brittle. Moreover, there would be no reasonable expectation of success in combining the teachings of Gao et al. with those of Pacetti et al., since one skilled in the art would expect that a brittle coating such as calcium phosphate would fracture if used on a flexible substrate such as a stent, rendering the coated stent unsuitable for its intended purpose.

Further, one skilled in the art would not have contemplated using a calcium phosphate coating in a blood vessel. Such materials are well known for use in orthopedic devices as an osseointegrative material. In contrast, there is reason for osseointegration in a blood vessel, and thus calcium phosphate would not have been considered as a sutable material for coating a stent.

Accordingly, Applicants respectfully submit that the Examiner has failed to raise a *prima facie* case of obviousness with respect to claims 1-4, 7, 9, 12 and 13. Accordingly, the Examiner is respectfully requested to reconsider and withdraw this rejection.

Compliance of Claims 5 and 37 with 35 U.S.C. §103

The Office Action rejects claims 5 and 37 as unpatentable over Gao et al. and Pacetti et al. as applied to claim 1, further in view of Choi et al. 2000 (*Biomaterials* 21(5):469-473).

To Applicants' understanding, Choi et al. teach deposition of hydroxyapatite on metals such as titanium. Choi et al. do not teach or suggest the application of coatings on substrates that

undergo deformation after deposition of the coatings, and do not suggest a flexible calcium phosphate coating as claimed in amended claim 1. Accordingly, Choi et al. fail to remedy the deficiencies noted above with respect to the combination of Gao et al. and Pacetti et al. The Examiner is accordingly requested to withdraw this rejection.

Compliance of Claim 11 with 35 U.S.C. §103

The Office Action rejects claim 11 as unpatentable over Gao et al. and Pacetti et al. as applied to claims 1, 2, 3-4, 7, 9, 12 and 13, further in view of Falotico et al., US 2001/0029351.

To Applicants' understanding, Falotico et al. disclose standard methods for coating a stent, i.e. either the use of discrete pockets or reservoirs within the metal stent itself, or a polymer coating, which is a deformable material that can withstand the deformation of a stent. Falotico et al. do not disclose or suggest the use of a rigid material such as a ceramic, e.g. a calcium phosphate, for coating a stent. Accordingly, Falotico et al. fails to remedy the deficiencies noted above with respect to the combination of Gao et al. and Pacetti et al. The Examiner is accordingly requested to withdraw this rejection.

Compliance of Claim 38 with 35 U.S.C. §103

The Office Action rejects claim 38 as unpatentable over Gao et al. and Pacetti et al. as applied to claims 1-4, 7, 9, 12 and 13, further in view of Teller et al., US 5,759,376.

To Applicants' understanding, Teller et al. disclose a method for the electrochemical deposition of hydroxyapatite onto metal and ceramic surfaces. Teller et al. do not disclose the coating of a deformable medical device such as a stent. Further, Teller et al. disclose that the typical layer thickness is in the range of 5-25 μm (Teller et al. at Abstract; column 2 lines 34-37; and Example 6). Thus, not only does Teller et al. fail to remedy the deficiencies noted with respect to the combination of Gao et al. and Pacetti et al., as discussed above, but Teller et al. arguably teach away from using a coating having a thickness of no more than 1 μm as claimed, because a typical layer thickness of 5-25 μm is disclosed, and is characterized as being "an optimum layer thickness" in the Abstract of Teller et al. Accordingly, Applicants respectfully submit that no *prima facie* case of obviousness has been established with respect to claim 38. The Examiner is, therefore, respectfully requested to withdraw the rejection of claim 38.

Reconsideration

It is believed that all claims of the present application are now in condition for allowance.

Reconsideration of this application is respectfully requested. If the Examiner believes that a teleconference would expedite prosecution of the present application the Examiner is invited to call the Applicant's undersigned attorney at the Examiner's earliest convenience.

Any amendments or cancellation or submissions with respect to the claims herein is made without prejudice and is not an admission that said canceled or amended or otherwise affected subject matter is not patentable. Applicant reserves the right to pursue canceled or amended subject matter in one or more continuation, divisional or continuation-in-part applications.

Please grant any extensions of time required to enter this response and charge any fees in addition to fees submitted herewith that may be required to enter/allow this response and any accompanying papers to our deposit account 02-1037 and credit any overpayments thereto.

Respectfully submitted,

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